

Date Received:

Date Reviewed:

Action:

- ☐ Approved  
☐ Not Approved

Laboratory name: \_\_\_\_\_

Laboratory Director: \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_

Telephone: \_\_\_\_\_ Fax: \_\_\_\_\_

**NAHLN Laboratory Qualification Checklist  
for  
Membership of a Veterinary Diagnostic Laboratory**

MEMORANDUM to Laboratory Director and Responsible Official (RO) of Candidate National Animal Health Laboratory Network (NAHLN) Testing Laboratory.

SUBJECT: NAHLN Laboratory Qualification Checklist for Membership of a Veterinary Diagnostic Laboratory

1. Have you reviewed your shipping and receiving activities, guidelines and SOPs to ensure consistency with agent-specific issues of laboratory safety, sample and specimen handling, worker training, select agent materials and facility requirements associated with the agent-specific functional designations for which you are applying? General pertinent overview information on high consequence livestock pathogens and toxins and select agents can be obtained at [www.aphis.usda.gov/vs/ncie/bta.html](http://www.aphis.usda.gov/vs/ncie/bta.html) and [www.cdc.gov/od/sap](http://www.cdc.gov/od/sap) and is delineated in the DHHS/CDC publication, Biosafety in Microbiological and Biomedical Laboratories, 4<sup>th</sup> edition ([www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm](http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm)).
- ☐ **Yes, I have reviewed our shipping and receiving activities to ensure consistency with current NAHLN standards.**
2. Given the above, and initial review of the respective NAHLN protocols, which agent-specific testing designations are you applying for? Please list the agent, sample types, and test types. These initial self-classifications signify that your lab is currently capable of performing tests of this type, possesses the necessary equipment and personnel trained in its use, and would be willing to perform the tests in matrices such as animal, food, and environmental samples.

- ☐ **Yes, my laboratory is currently capable of performing the agent-specific test types being applied for, possesses the necessary equipment and personnel trained in its use, and would be willing to perform the tests on the specified sample matrices.**

**Agent**

**Sample Type**

**Test Type**

3. A plan for operational flow of animal, food and low-risk environmental samples to and between state and federal veterinary diagnostic laboratories is essential. Have you reviewed standard operating procedures with your state and federal regulatory officials (State Veterinarian, AVIC, etc.) to ensure appropriate flow of samples and assay results, including protocols for the confidential alert and notification of appropriate state and federal officials and agencies?

- ☐ **Yes, I have reviewed standard operating procedures for sample accession, NAHLN testing and reporting, and notification in our animal disease diagnostic laboratory with the State Veterinarian, the Area Veterinarian in Charge (AVIC), and other appropriate officials.**

4. Do you agree to adhere to the NAHLN established standard testing procedures (within the agent-specific protocol) as well as use of NAHLN standardized reagents and controls when testing and reporting testing results on the designated high consequence livestock pathogens and other biothreat agents?

- ☐ **Yes, I agree to adhere to the NAHLN testing protocol and standards for use of NAHLN reagents and controls.**

5. Have you established operational relationships with the WMD (Weapons of Mass Destruction) Coordinator at your appropriate/local FBI Field Office? Laboratory testing of specimens and samples related to a bioterrorism event will involve the need for secure storage and chain-of-custody procedures, as well as procedures for evidence collection and preservation to support potential evidentiary requirements of the FBI. If FBI assistance is needed, contact Dr. Douglas L. Anders at 703-632-4652 or danders@fbiacademy.edu.

☐ **Yes, I have established communications and operational relationships with the appropriate FBI/WMD Coordinator.**

6. Do you agree to comply with the NAHLN Notification Plan for Potential Animal, Food, and/or Environmental-Related Foreign Animal Disease and/or Bioterrorism Events (i.e. scenario in which an animal sample becomes suspect during the course of testing in the microbiology laboratory)? This plan states:

*When a Veterinary Diagnostic Laboratory approved for a specific agent obtains a presumptive-level identification of a possible foreign animal disease (FAD) using the defined testing procedure contained in the current agent-specific protocols (provided by the NAHLN), the 1) State Veterinarian and their respective state notification line, and 2) United States Department of Agriculture (APHIS) will be immediately notified. When there is heightened suspicion of a bioterrorism event, the Federal Bureau of Investigation emergency response officials also will be immediately notified. Given the potential sensitivity of this information, procedures for confidential and secure communications may need to be defined in advance and address issues of consistent and timely exchange of information in the event of an emergency response situation. It is important that this communication relationship be properly maintained in order to foster network integrity and future exchange of time-sensitive information. It should be kept in mind that some notification thresholds might vary according to challenges unique to a specific biological threat agent.*

☐ **Yes, I agree to comply with the General NAHLN Notification Plan for Potential Foreign Animal Disease and/or Bioterrorism Events.**

7. For NAHLN laboratories involved with the use, transfer and possession of high consequence livestock pathogens and toxins and select agent materials, the Responsible Official will need to facilitate registration with the USDA Biological Agent and Toxin Registration Program ([www.aphis.usda.gov/vs/ncie/bta.html](http://www.aphis.usda.gov/vs/ncie/bta.html)) or the CDC Select Agent Program ([www.cdc.gov/od/sap](http://www.cdc.gov/od/sap)) as appropriate, and be compliant with current regulations of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and USA Patriot Act of 2001. Materials (protocols, assays, reagents, controls, select agents, etc.) distributed by the NAHLN are for purposes related to animal health practice, multi-center validation studies, test validation and the need to participate in the network proficiency testing program. NAHLN materials are not intended for research use. *There will be no distribution of high consequence livestock pathogens and toxins or select agents or of any NAHLN materials outside of the receiving facility to which the NAHLN originally transferred the materials.*

☐ **Yes, I agree to participate in the NAHLN proficiency testing program, assure that our laboratory personnel will not distribute any NAHLN materials outside of the laboratory, and be compliant with current high consequence livestock pathogens and toxins and select agent regulations.**

8. By signing below, the facility's Laboratory Director and Responsible Official (RO) confirm that the preceding items have been properly reviewed and addressed, and therefore assume responsibility for the requested materials, assure sufficient internal security to control access to NAHLN materials and agents, assure there will be no transfer of these materials and agents to any third party, and accept responsibility for all risks associated with handling these materials and agents.

\_\_\_\_\_  
Signature of Laboratory Director

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name, Title

Laboratory Director Phone Number \_\_\_\_\_

Laboratory Director Email \_\_\_\_\_

\_\_\_\_\_  
Signature of RO

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name, Title

RO Phone Number \_\_\_\_\_

RO Email \_\_\_\_\_

Laboratory Official Point of Contact for High Consequence Livestock Pathogens and Toxins and  
Select Agents:

Name:

Title:

Phone:

Email:

Alternate Laboratory Point of Contact for High Consequence Livestock Pathogens and Toxins  
and Select Agents:

Name:

Title:

Phone:

Email:

9. By signing below, the State Veterinarian, Federal Area Veterinarian in Charge (AVIC), and State Department of Agriculture Director (or the equivalent authority) indicate that they have read this document, discussed its contents with the Laboratory Director, and understand and agree to abide by all regulations and policies governing confidential reporting of disease outbreaks.

\_\_\_\_\_  
Signature of State Veterinarian

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name, Title

State Veterinarian Phone Number \_\_\_\_\_

State Veterinarian Email \_\_\_\_\_

\_\_\_\_\_  
Signature of AVIC

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name, Title

AVIC Phone Number \_\_\_\_\_

AVIC Email \_\_\_\_\_

\_\_\_\_\_  
Signature of State Dept. of Agriculture Director (or equivalent)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name, Title

State Dept. of Agriculture Director (or equivalent) Phone Number \_\_\_\_\_

State Dept. of Agriculture Director (or equivalent) Email \_\_\_\_\_

***Failure to comply with all regulations and policies by any party may result in immediate loss of the laboratory's approval to conduct NAHLN testing for high consequence livestock pathogens and BT agents.***